

United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.usplo.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-----------------------|----------------------|-----------------------|------------------|
| 10/645,847 | 08/22/2003 | William E. Klunk | 076333-0323 | 8143 |
| FOLEY AND LARDNER LLP SUITE 500 | | EXAMINER | | |
| | | e • | JONES, DAMERON LEVEST | |
| 3000 K STREET NW WASHINGTON, DC 20007 | | | ART UNIT | PAPER NUMBER |
| ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,, | , _ 0 _ 0 0 0 0 | | 1618 | |
| SHORTENED STATUTO | RY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE | |
| 3 M(| ONTHS | 01/17/2007 | PAPER | |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| Office Action Summary 10/645,847 KLUNK ET AL. | | | | | |
|---|--|--|--|--|--|
| D. L. Jones 1618 The MAILING DATE of this communication appears on the cover sheet with the correspondence address | | | | | |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address | | | | | |
| | | | | | |
| a arram car cooks. | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | | | | |
| Status | | | | | |
| 1)⊠ Responsive to communication(s) filed on <u>13 November 2006</u> . | | | | | |
| 2a)⊠ This action is FINAL . 2b)□ This action is non-final. | | | | | |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is | | | | | |
| closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. | | | | | |
| Disposition of Claims | | | | | |
| 4)⊠ Claim(s) <u>1-27</u> is/are pending in the application. | | | | | |
| 4a) Of the above claim(s) 2, 3, 5-7, 10-13, and 15-27 is/are withdrawn from consideration. | | | | | |
| 5) Claim(s) is/are allowed. | | | | | |
| 6)⊠ Claim(s) <u>1,4,8,9 and 14</u> is/are rejected. | | | | | |
| 7) Claim(s) is/are objected to: | | | | | |
| 8) Claim(s) are subject to restriction and/or election requirement. | | | | | |
| Application Papers | | | | | |
| | | | | | |
| 9) The specification is objected to by the Examiner. | | | | | |
| 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). | | | | | |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | |
| Priority under 35 U.S.C. § 119 | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: | | | | | |
| Certified copies of the priority documents have been received. | | | | | |
| 2. Certified copies of the priority documents have been received in Application No | | | | | |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage | | | | | |
| application from the International Bureau (PCT Rule 17.2(a)). | | | | | |
| * See the attached detailed Office action for a list of the certified copies not received. | | | | | |
| | | | | | |
| | | | | | |
| Attachment(s) | | | | | |
| 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) | | | | | |
| 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) Paper No(s)/Mail Date | | | | | |
| 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 5) Notice of Informal Patent Application 6) Other: | | | | | |

Application/Control Number: 10/645,847

Page 2

Art Unit: 1618

ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of the amendment filed 11/13/06 wherein

claims 1 and 2 were amended.

Note: Claims 1-27 are pending.

CLARIFICATION OF THE RECORD

2. Applicant's request for reconsideration of the finality of the rejection mailed

8/11/06 is persuasive and, therefore, the finality of that action is WITHDRAWN.

RESPONSE TO APPLICANT'S ARGUMENTS/AMENDMENT

3. The Applicant's arguments and/or amendment filed 11/13/06 to the rejection of

the claims made by the Examiner under 35 USC 102, 103, and/or double patenting

have been fully considered and deemed persuasive for the reasons set forth below.

Therefore, the said rejections are hereby withdrawn.

102 Rejection

The 102 rejection is WITHDRAWN because Applicant has amended the claims

to overcome the rejection.

103 Rejection

The 103 rejection is WITHDRAWN because Applicant has amended the claims

to overcome the rejection.

Double Patenting Rejection

The double patenting rejection is WITHDRAWN because Applicant has amended

the claims to overcome the double patenting rejection.

Application/Control Number: 10/645,847 Page 3

Art Unit: 1618

WITHDRAWN CLAIMS

4. Claims 2, 3, 5-7, 10-13, and 15-27 are withdrawn from further consideration by the Examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention/species.

NEW GROUNDS OF REJECTION

112 Second Paragraph Rejections

- 5. The following is a quotation of the second paragraph of 35 U.S.C. 112:
 The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 6. Claims 1, 4, 8, 9, and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 4, 8, 9, and 14: The claims as written are ambiguous. In particular, independent claim 1 is confusing because in lines 10-11, the claim reads 'is substituted with a radioactive halo when R2 is hydrogen'. In particular, the phrase is confusing because the amended claim does not allow the R2 to be hydrogen. It should be noted that since claims 4 and 14 depend on independent claim 1, those claims are also vague and indefinite. In addition, lines 12-15 of independent claim 1 are confusing because the conditions that Applicant has set forth in the claims are valid for R2 = hydrogen, but the amended claim does not allow the variable R2 to be hydrogen.

102 REJECTION

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Application/Control Number: 10/645,847

Art Unit: 1618

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

8. Claims 1, 4, and 14 are rejected under 35 U.S.C. 102(a) as being anticipated by Wang et al (Journal of Molecular Neuroscience, 2002, Vol. 19, Nos. 1-2, pp. 11-16).

Wang et al disclose the synthesis and evaluation of 2-(3'-iodo-4'-aminophenyl)-6-hydroxybenzothiazole for in vivo quantitation of amyloid deposits in Alzheimer's disease (see entire document, especially, abstract; page 13, 'Materials and Methods'; and 'page 13, 'Results'). In particular, on page 13, Scheme 2, Compound 6 is disclosed that meet the limitations of the instant invention when R1 = OH; R2 = radioactive halogen (radioiodine); and both R3 and R4 are hydrogen atoms.

103 REJECTION

- 9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 10. Claims 1, 8, 9, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang et al (Journal of Molecular Neuroscience, 2002, Vol. 19, Nos. 1-2, pp. 11-16).

Wang et al (see discussion above) fail to disclose other radiolabeled halogens in the 3'-position of the 2-(3'-halogen-4'-aminophenyl)-6-hydroxybenzothiazole compound disclosed on page 13, Scheme 2.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to replace the radioiodine with other radiolabeled halogens (radiofluorine, etc.) because a skilled practitioner in the art would recognize that the substitution of one halogen with another would not drastically alter the overall properties of the overall complex.

COMMENTS/NOTES

- 11. It is duly noted that Applicant has amended the claims to <u>exclude the elected</u>

 <u>speci</u>es, the species of Formula I wherein R1 is OH; R2 is hydrogen; and R4 is ¹¹CH3.
- 12. The election of species requirement was not expanded beyond R1 = OH; R2 = radioactive halogen; R3 = hydrogen; and R4 = hydrogen because prior art was found which could be used to reject Applicant's claims.
- 13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

Art Unit: 1618

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Note: The finality is proper because Applicant has amended the claims to overcome the cited prior art rejections. Thus, it was necessary for the Examiner to expand the search to another species but since prior art was found for that species, the search was not further expanded.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m.. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Primary Examiner
Art Unit 1618

January 8, 2007